

Appl. No.: 10/070,590  
Group Art Unit: 1616  
Applicants' Response to Paper No. 9

### REMARKS

Claims 8-17 are currently pending in the present application.

In Paper No. 9, the Examiner maintains the rejection of claims 8-17 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 6,261,598 of Runge, *et al.*, (hereinafter referred to as "Runge"), in view of either U.S. Pat. No. 5,976,568 of Riley, (hereinafter referred to as "Riley") or U.S. Pat. No. 6,205,354 of Gellermann, *et al.*, (hereinafter referred to as "Gellermann"), and makes the rejection final. Specifically, the Examiner contends that Runge "explicitly teach[es] combinations of  $\beta$ -carotene, lycopene and lutein having claimed ratios by weight." (*See*, Paper No. 9, ¶ 3, p. 2). The Examiner further contends that both Riley and Gellermann teach carotenoid-containing oral formulations useful for protecting against UV radiation, and thus, the Examiner argues that one of ordinary skill in the art would have been motivated to use the compositions taught by Runge in accordance with the teachings of either Riley or Gellermann. (*See*, Paper No. 9, ¶ 3, p. 3).

Applicants respectfully traverse the Examiner's rejection and the arguments and contentions set forth in support thereof for the following reasons.

First, Applicants respectfully submit that Runge does not explicitly teach compositions in accordance with the claimed invention. Applicants' claimed invention is directed to methods of improving the sun protection factor of human skin and methods of inhibiting the aging of human skin, the methods comprising: (i) providing a composition comprising (a)  $\beta$ -carotene, (b) lutein and (c) lycopene, in a ratio by weight (a):(b):(c) of from 1:0.5:0.5 to 1:1.5:1.5; and (ii) orally administering the composition to a human.

The ratio by weight of  $\beta$ -carotene, lutein and lycopene in the compositions administered in accordance with Applicants' claimed invention is from 1:0.5:0.5 to 1:1.5:1.5. Runge discloses broad ranges of  $\beta$ -carotene, lycopene and lutein components which range from 0.05 to 20 parts of lycopene and from 0.05 to 20 parts of lutein for each 1 part of  $\beta$ -carotene. While 0.5 to 1.5, as claimed by Applicants, does fall within the extremely broad range of 0.05 to 20 disclosed in Runge, Runge fails to contain a single specific reference to the narrower range

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claimed by Applicants, nor does Runge contain any specific example which falls within the range claimed by Applicants.

Runge contains five examples. In Example 1, 350 grams of crystalline  $\beta$ -carotene are combined with 180 grams of crystalline lycopene and 70 grams of crystalline lutein. (See, Runge, col. 4, lines 43-58). This equates to a ratio by weight of 1.0:0.514:0.2 (350:180:70). Thus, in Example 1, the composition lacks the claimed amount of lutein. In Example 2, 30 grams of  $\beta$ -carotene are combined with 10 grams of lutein and 10 grams of lycopene (based on percentage of actives in each dispersion used in the example). (See, *id.* at col. 4, line 61, through col. 5, line 2). This equates to a ratio by weight of 1.0:0.33:0.33. Thus, in Example 2, neither lycopene or lutein is present in the claimed amount. In Example 3, 150 grams of crystalline  $\beta$ -carotene are combined with 50 grams of crystalline lycopene and 25 grams of crystalline lutein. (See, Runge, col. 5, lines 5-25). This equates to a ratio by weight of 1.0:0.33:0.167. Thus, in Example 3, the composition lacks the claimed amount of both lutein and lycopene. In Example 4, 22 grams of crystalline  $\beta$ -carotene are combined with 8 grams of crystalline lycopene and 4 grams of crystalline lutein. (See, Runge, col. 5, lines 28-49). This equates to a ratio by weight of 1.0:0.36:0.18. Thus, in Example 4, the composition lacks the claimed amount of both lutein and lycopene. Finally, in Example 5, 600 grams of crystalline  $\beta$ -carotene are combined with 300 grams of crystalline lycopene and 100 grams of crystalline lutein. (See, Runge, col. 6, lines 1-17). This equates to a ratio by weight of 1.0:0.5:0.167. Thus, in Example 5, the composition lacks the claimed amount of lutein.

Applicants have surprisingly found that the mixture of these three particular carotenoids in the claimed ratios is particularly well-suited to increasing the sun protection factor of the skin and simultaneously inhibiting the aging of the skin. (See, Applicants' Specification, p. 3, line 26, through p. 4, line 3).

Thus, while Runge discloses compositions containing each of the three components, the reference fails to teach or suggest the claimed range of ratios by weight. It is fairly well-settled that where a prior art reference discloses an overlapping range, that a *prima facie* case of obviousness may be established, but that such a *prima facie* case of obviousness is

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rebutted by evidence showing that the claimed narrower range is critical to the results obtained, or that the prior art reference teaches away from the claimed invention. In the instant application, Applicants have shown that compositions containing the claimed components in amounts within the claimed ratio by weight range exhibit significantly improved sun protection results and that this improvement is surprising. (*See*, Applicants' Specification, p. 3, line 26, through p. 4, line 3; and Examples). Applicants note that the Federal Circuit has held that "the PTO *must* consider" comparisons in the specification when determining whether the claimed invention is unobvious. (*See, In re Soni*, 34 USPQ2d 1684, 1687 (Fed. Cir. 1995) (*emphasis added*), citing *In re Margolis*, 228 USPQ 940 (Fed. Cir. 1986)).

Thus, Applicants respectfully submit that while the broad range disclosed in Runge overlaps the narrower range claimed in the instant application, that the claimed range would not have been obvious to one of ordinary skill in the art at the time of invention based upon Runge as the reference fails to recognize the criticality of the claimed range with respect to the improvement in skin sun protection factor.

Second, even if one were to assume, for argument's sake, that the claimed narrower range of ratios by weight of from 1.0:0.5:0.5 to 1.0:1.5:1.5 was obvious in view of the broader 1.0:0.05:0.05 to 1:20:20 range disclosed in Runge, neither secondary reference remedies the acknowledged deficiency of Runge which fails to teach the administration of compositions in accordance with the claimed invention for the improvement of the skin's sun protection factor.

The Examiner has argued that each of Riley and Gellermann teaches the administration of carotenoid compositions for protecting the skin from UV radiation damage, and thus, that one of ordinary skill would have found it obvious to use the compositions of Runge for similar purposes.

Applicants respectfully disagree and submit that neither Riley or Gellermann suggests the use of the specific compositions disclosed by Runge for improving the skin's sun protection factor, and that the Examiner is advancing an argument based, at best, on an "obvious-to-try" rationale, which is an inappropriate standard upon which to base an obviousness rejection. Riley, in the portions cited by the Examiner, simply discloses that lycopene may

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decrease the risk of skin damage secondary to ultraviolet exposure. Gellermann notes that several of the carotenoids have been found to be associated with healthy skin and that carotenoids in general are thought to act as free radical scavengers which may protect the skin from reactive oxygen species that can be formed upon excessive exposure to ultraviolet radiation. However, nowhere does either Riley or Gellerman teach or suggest that compositions specifically containing  $\beta$ -carotene, lycopene and lutein should be administered to improve the skin's sun protection factor. The Examiner argues that based upon Riley and Gellermann, it would be obvious to administer any composition containing a carotenoid for such a purpose. Much less than the required "desirability" which must be disclosed in the prior art to support an obviousness rejection, this is simply an "obvious-to-try" rationale that is legally insufficient to support an obviousness rejection. Applicants have surprisingly found that  $\beta$ -carotene, lutein AND lycopene, *in the claimed ratios by weight*, can be orally administered to improve the skin's sun protection factor. This is not suggested by either Riley or Gellermann. In fact, neither Riley or Gellermann contains any teaching which would suggest to one of ordinary skill in the art that the specifically claimed combination would have a result better than any single carotenoid.

Applicants respectfully submit that the Examiner has failed to establish obviousness based upon the cited combination of references. Withdrawal of the rejection of claims 8-17 under §103(a) is respectfully requested.

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In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejection and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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